Today's Objectives

1 Importance of Audit Trails & Documentation

2 Anatomy of an Audit Trail

3 Common Paths You Should Follow

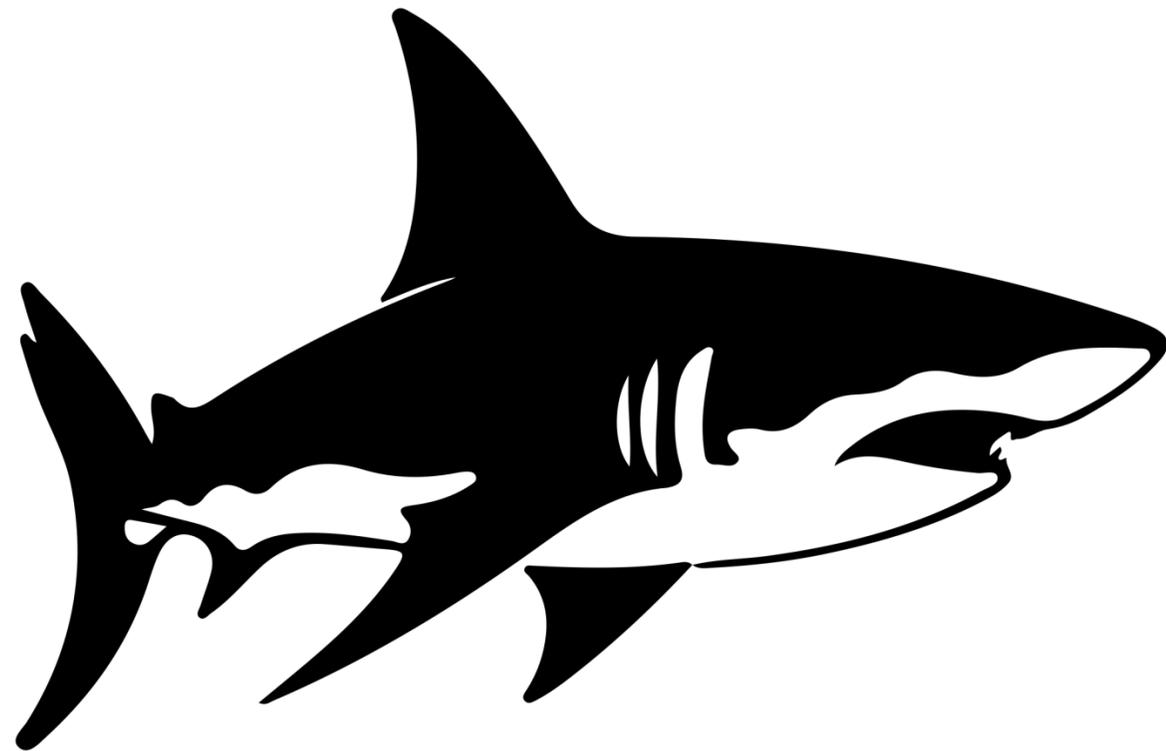**4** Documenting Objective Evidence

Team Check-in

What challenges have you faced in your organization
when it comes to effectively conducting internal audits?

- Seems like a chore of a requirement...
- Not getting any real value from them...
- Only hitting the surface of our QMS...
- Using a checklist approach...

Weak Audits?

Why care about audit trails?

"I'd rather just use a checklist and call it a day"

1 Traceability & Transparency

2 Responsibility & Ownership

3 Audit Readiness

4 Identifies Bottlenecks

5 Data Driven Decisions

6 Risk Management

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1. Traceability & Transparency

Provides a detailed, chronological record of all transactions and activities.

2. Responsibility & Ownership

Identifies individuals responsible for specific tasks, ensuring accountability. Who did what and when.

3. Audit Readiness

Prepares the organization for external audits by providing well-documented evidence.

4. Identifies Bottlenecks

Provides insights into process performance and efficiency.

5. Data Driven Decisions

Enhances the ability to make informed, data-driven decisions.

6. Risk Management

Provides a clear record of actions taken to address potential risks

"Watch the little things; a small leak will sink a great ship."

Look for Alignment
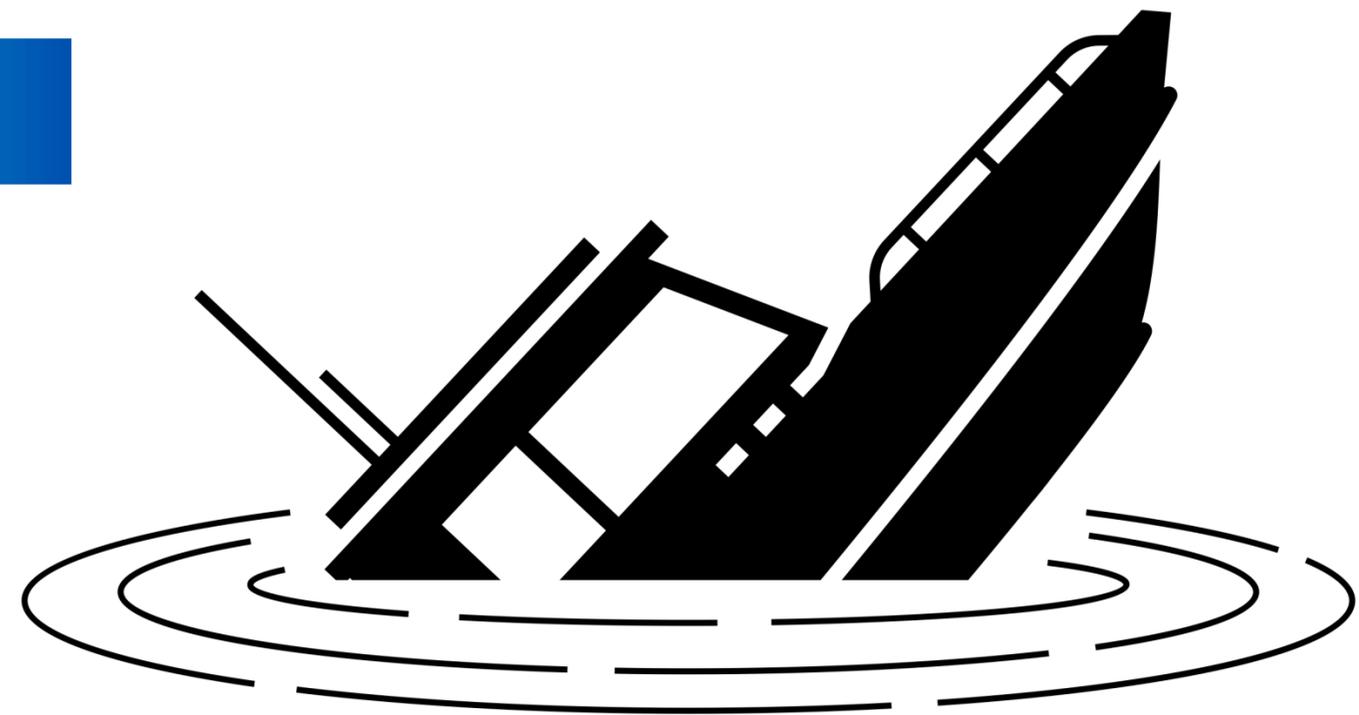
What is an audit trail?

... a detailed and chronological record that traces the sequence of activities in a system, process, or procedure

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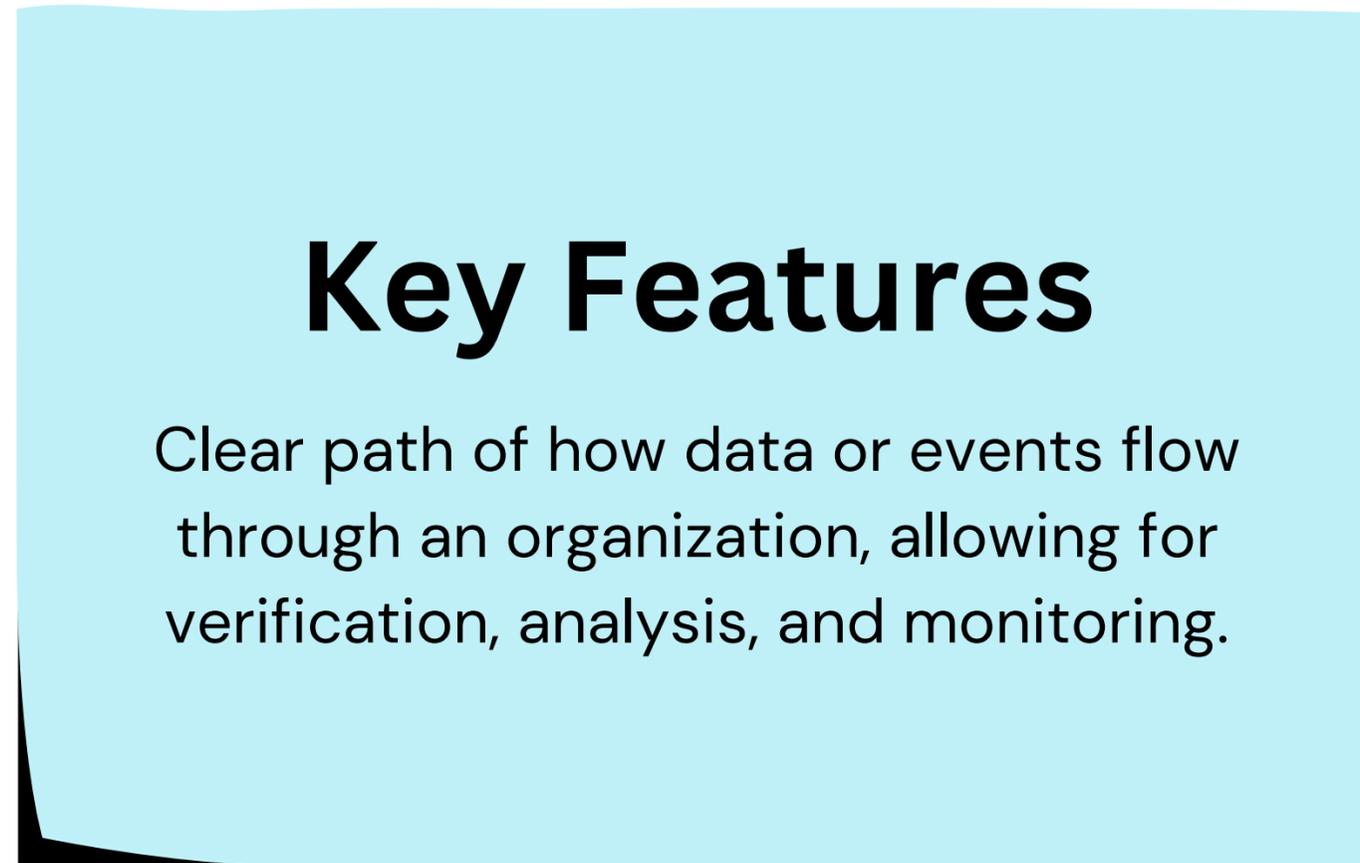1. Chronological Sequence

2. Detail – Oriented

3. Traceability

Key Features

Clear path of how data or events flow through an organization, allowing for verification, analysis, and monitoring.

4. Transparency

5. Verification & Validation

6. Compliance

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Chronological Sequence

- An audit trail records events or transactions in the exact order they occurred.

- Clear timeline of activities

Example: In a production process, an audit trail might show the exact times when materials were received, when production started, when inspections were conducted, and when the final product was shipped.

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Detailed Oriented

- Captures info about each activity:
- including who performed the action,
- what was done,
- when it was done,
- where it occurred,
- why it happened.

Example: For a quality inspection, the audit trail would document the inspector's name, the specific tests performed, the results, the date and time of the inspection, and the location where it was conducted.

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Traceability

- Allows you to trace back from the end result to the originating event
- Accountability for actions throughout the entire process

Example: In a supply chain audit, traceability might involve tracking a product from its initial order, through production, quality checks, and final delivery, ensuring each step is documented.

Transparency

- All actions are visible and can be reviewed by authorized personnel
- Transparency builds trust

Example: A transparent audit trail in financial transactions would show all approvals, payments, and reconciliations, making it clear who authorized and processed each transaction.

Verification & Validation

- Verification of data integrity and validation of processes
- Identify discrepancies, errors, or unauthorized actions
- Compliant with standards and procedures

Example: In a manufacturing environment, verification and validation might involve cross-checking the calibration records of machinery used in production. For instance, if a particular machine is used to manufacture aerospace components, the audit trail would include records of regular calibration checks. An auditor would verify that the calibration was performed according to the schedule, by qualified personnel, and using certified equipment.

Compliance

- Demonstrating compliance with legal, regulatory, and internal policies
- Providing evidence of adherence

Example: In aviation distribution, compliance with regulations such as those set by the Federal Aviation Administration (FAA) is critical. For instance, when distributing aircraft parts, the audit trail would include records of part procurement, inspection, certification, and distribution.

Source Documents

Tangible proof that an activity took place

Auditors can cross-check source documents against recorded data to verify accuracy

Situation: A company needs to verify a supplier's delivery.

Action: Review purchase orders and delivery notes to confirm the delivery.

Outcome: Ensures the supplier fulfilled their obligations and supports accurate inventory records.

Purchasing:

- Purchase orders, invoices, receipts, delivery notes, certificates

Contract Review:

- Quote, customer specifications, sales orders, customer quality requirements

Operations:

- Pick tickets, packing lists, certificates, tags, drawings, customer specifications

Activity Logs

Helps in monitoring user actions and system activities.

Situation: An unexpected system shutdown occurs.

Action: Review system /operational logs to identify the cause.

Outcome: Quickly pinpoint and address the issue, minimizing downtime.

Purchasing:

- Receiving inspection records

Contract Review:

- Contract review document, risk assessment

Operations:

- In process inspection records, final inspection records, production travelers, test activities

User Info

Verifying that actions were performed by authorized personnel.

Situation: Unauthorized access to a secure system is detected.

Action: Review user access logs to identify the unauthorized user.

Outcome: Take steps to prevent future unauthorized access and hold the responsible party accountable.

- User acces to MRB cage
- User access to edit QMS documentation
- Users authorized for special processes
- Users authorized for inspection
- Users authorized to train staff
- Users authorized to perform their function

Compliance

Ensure internal operations align with organizational goals and regulatory requirements.

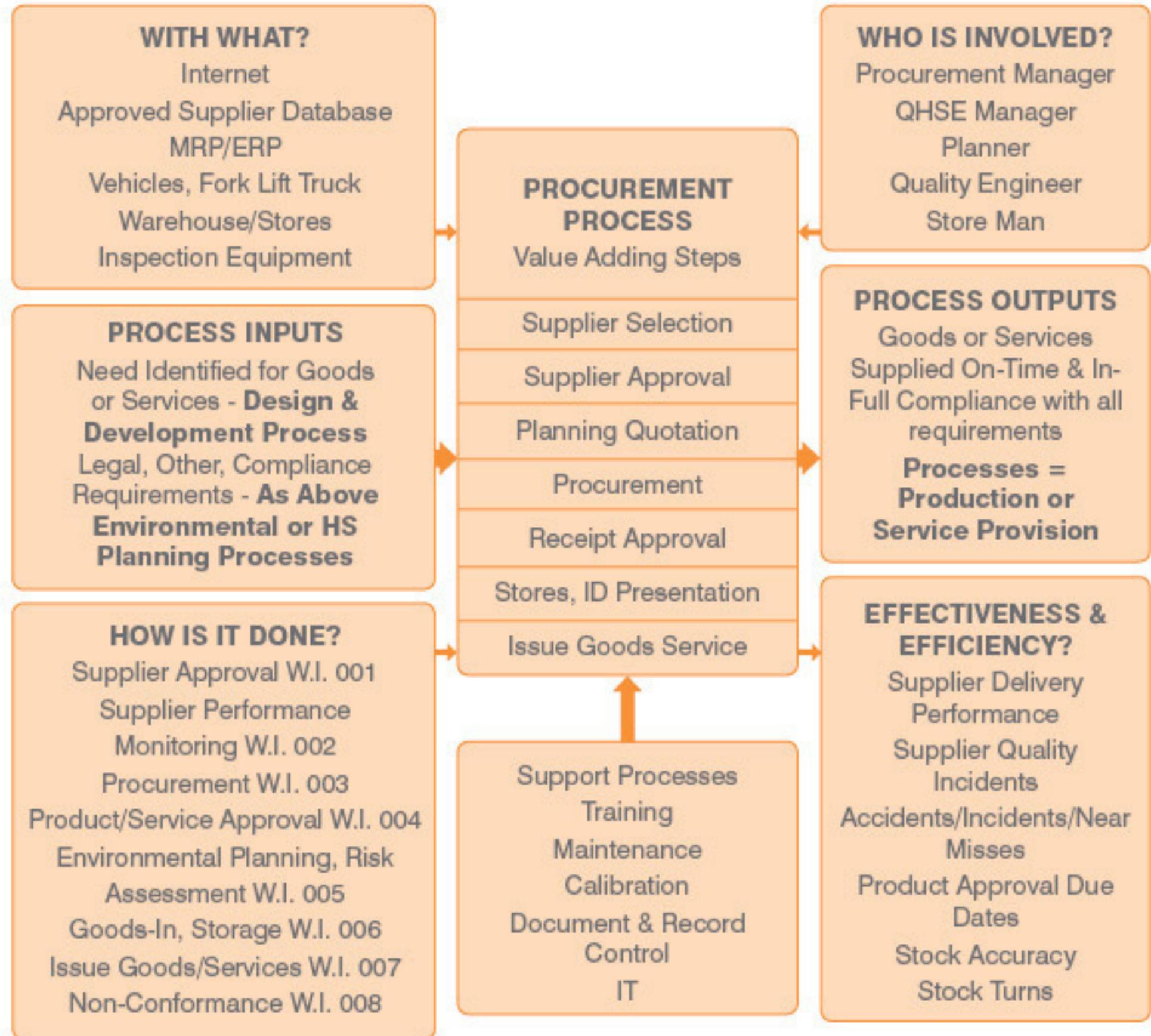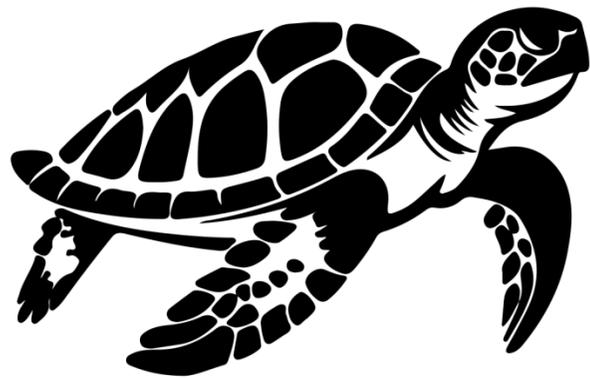**Situation**: Implementing a new production process.

Action: Document each step of the process, including approvals and modifications.

Compliance Check: Ensure documentation aligns with internal procedural guidelines.

- Compliance to internal procedures
- Say what we do, do what we say
- AS Compliance
- ISO Compliance

Turtle

When in doubt; use the turtle diagram to pick a starting point for your audit trail.

WITH WHAT?
Internet
Approved Supplier Database
MRP/ERP
Vehicles, Fork Lift Truck
Warehouse/Stores
Inspection Equipment

PROCESS INPUTS
Need Identified for Goods or Services - **Design & Development Process**
Legal, Other, Compliance Requirements - **As Above Environmental or HS Planning Processes**

HOW IS IT DONE?
Supplier Approval W.I. 001
Supplier Performance Monitoring W.I. 002
Procurement W.I. 003
Product/Service Approval W.I. 004
Environmental Planning, Risk Assessment W.I. 005
Goods-In, Storage W.I. 006
Issue Goods/Services W.I. 007
Non-Conformance W.I. 008

PROCUREMENT PROCESS
Value Adding Steps

Supplier Selection

Supplier Approval

Planning Quotation

Procurement

Receipt Approval

Stores, ID Presentation

Issue Goods Service

Support Processes
Training
Maintenance
Calibration
Document & Record Control
IT

WHO IS INVOLVED?
Procurement Manager
QHSE Manager
Planner
Quality Engineer
Store Man

PROCESS OUTPUTS
Goods or Services Supplied On-Time & In-Full Compliance with all requirements
Processes = Production or Service Provision

EFFECTIVENESS & EFFICIENCY?
Supplier Delivery Performance
Supplier Quality Incidents
Accidents/Incidents/Near Misses
Product Approval Due Dates
Stock Accuracy
Stock Turns

1. Data Collection

1 Source Identification:
- Identify key sources relevant to the audit scope

2 Accuracy and Completeness:
- Ensure collected data is accurate

3 Record the date and time for each data entry to establish a chronological order

Look for Alignment

2. Documentation

1 Record Keeping:
- Use consistent formats and templates to ensure clarity

2 Structure and Organization:
- Organize logically, clear headings and subheadings
- PEAR reports, Process Matrix, Overview

3 Note taking
- Highlight notes different colors to represent audit trails

Look for Alignment

3. Verification

1 Cross Verification:
- Cross–check data entries against original source documents and records to confirm accuracy.

2 Approval & Authorization:
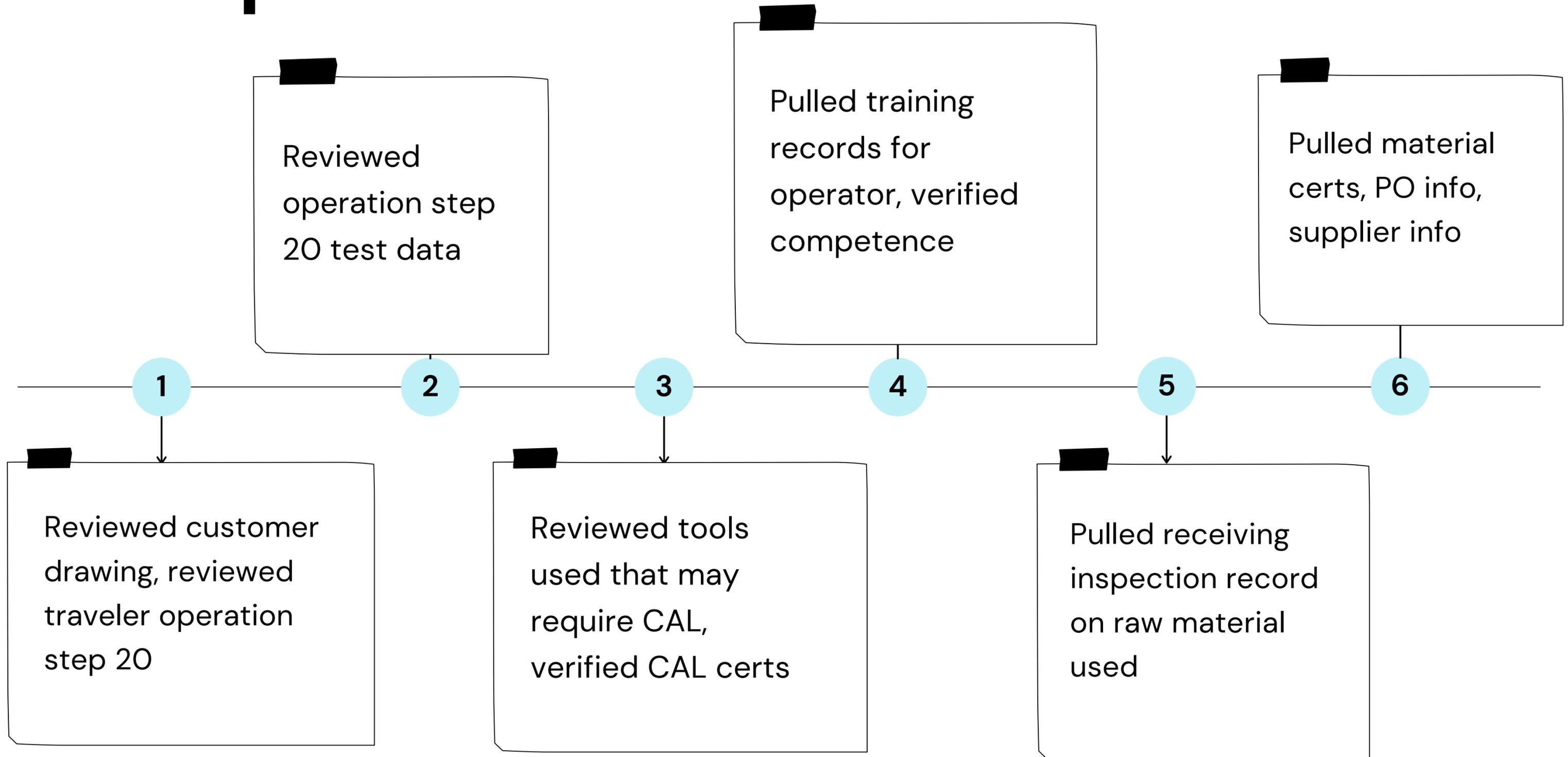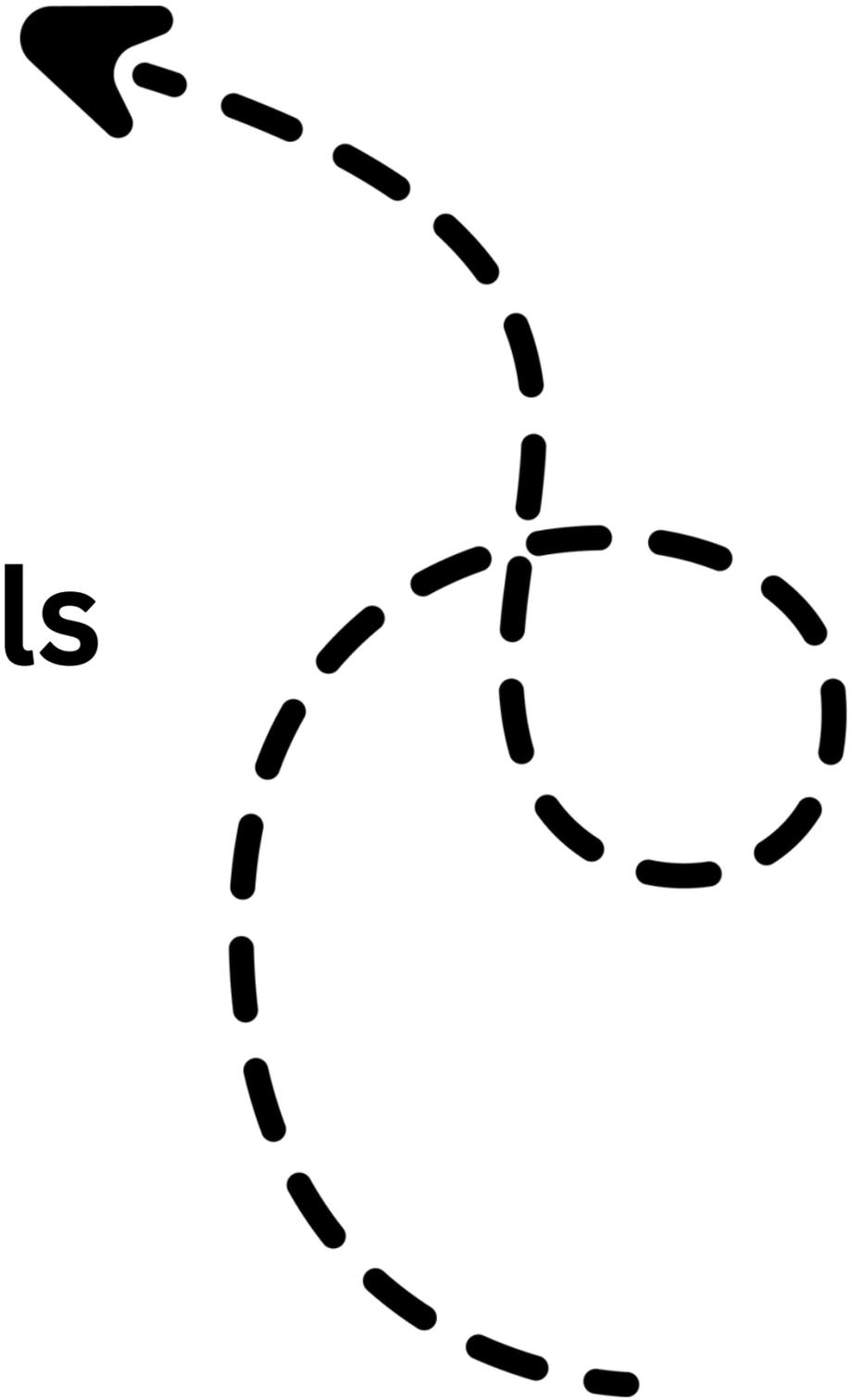- Reviewed and approved by authorized personnel

3 Analysis
- Analyze collected data to identify patterns, anomalies, and areas of concern

Look for Alignment

Example

1 Reviewed customer drawing, reviewed traveler operation step 20

2 Reviewed operation step 20 test data

3 Reviewed tools used that may require CAL, verified CAL certs

4 Pulled training records for operator, verified competence

5 Pulled receiving inspection record on raw material used

6 Pulled material certs, PO info, supplier info

Let's Build Some Trails

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You are part of the internal audit team for SkyHigh Distributors, a company that specializes in distributing aerospace components, such as avionics systems, hydraulic actuators, and engine parts, to various aircraft maintenance facilities and manufacturers.

Your task is to review the process flow of the organization and develop audit trails to ensure compliance with AS9120 standards and internal policies. During this review, you will also identify and address a potential finding.

Order Receipt and Processing:
- Customers place orders for aerospace components. Providing specifications required, testing required, DFAR / FAR clauses flowed down.
- Sales team processes the orders and confirms the details with customers.

Supplier Procurement:
- Required components are ordered from approved suppliers.
- Supplier certifications and qualifications are verified.
- One main supplier's quality has dropped significantly.

Incoming Inspection:
- Received components are inspected for quality and compliance with specifications.
- Non-conforming parts are identified and managed. MRB cage is locked.
- Some components are marked with red tape but no paperwork to go alongside.

Order Fulfillment:
- Customer orders are picked from inventory and prepared for shipping.
- Necessary documentation and certifications are included with each order.

Packaging and Shipping:
- Components are carefully packaged and labeled for shipment.
- Packages must weigh a certain amount as per customer specs.

Common Nonconformnaces

|		
Missing or Incomplete Documentation	**Non-conformance Process**	**Lack of Traceability**
Poor Record-Keeping Practices	**Unauthorized Access / Sequence of Operations**	**Lack of Training**

"Internal audit is not just about compliance, it's about enhancing the organization's ability to create value."
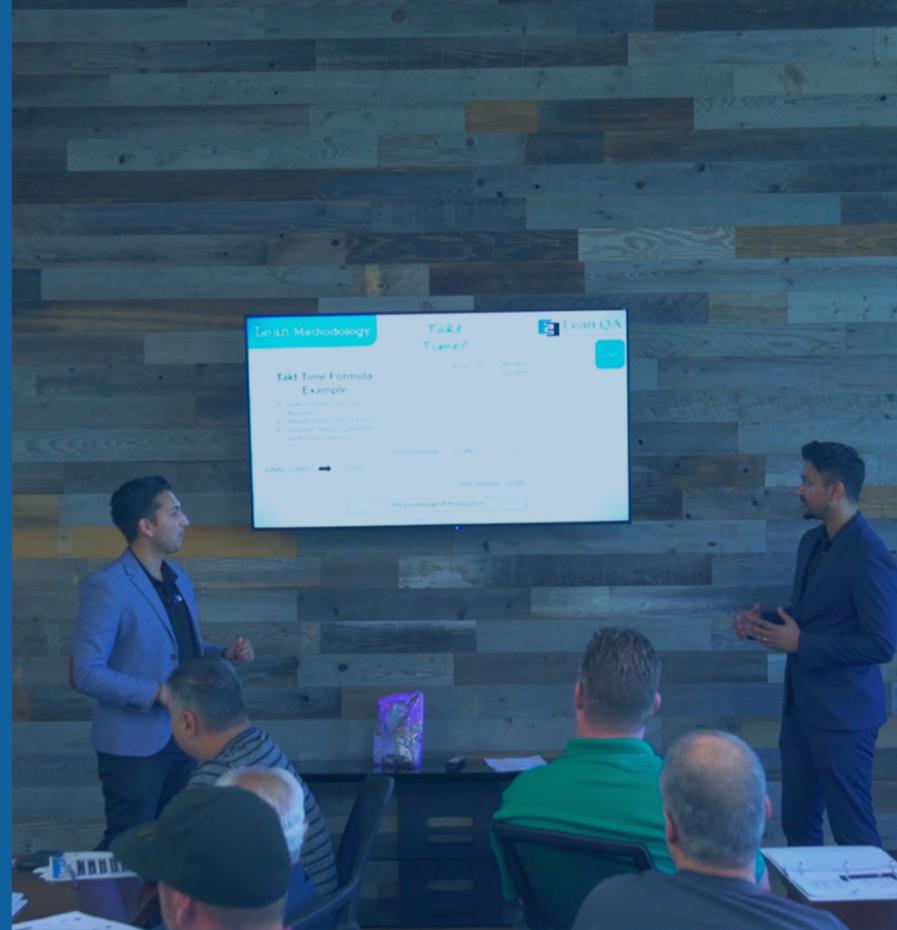
Q&A Panel

What potential audit trails are popping up in your mind for your organization?

Thank you for joining today's workshop. Lean QA can be your personal team of expert auditors crafting your audit trails and helping your organization focus on creating value.
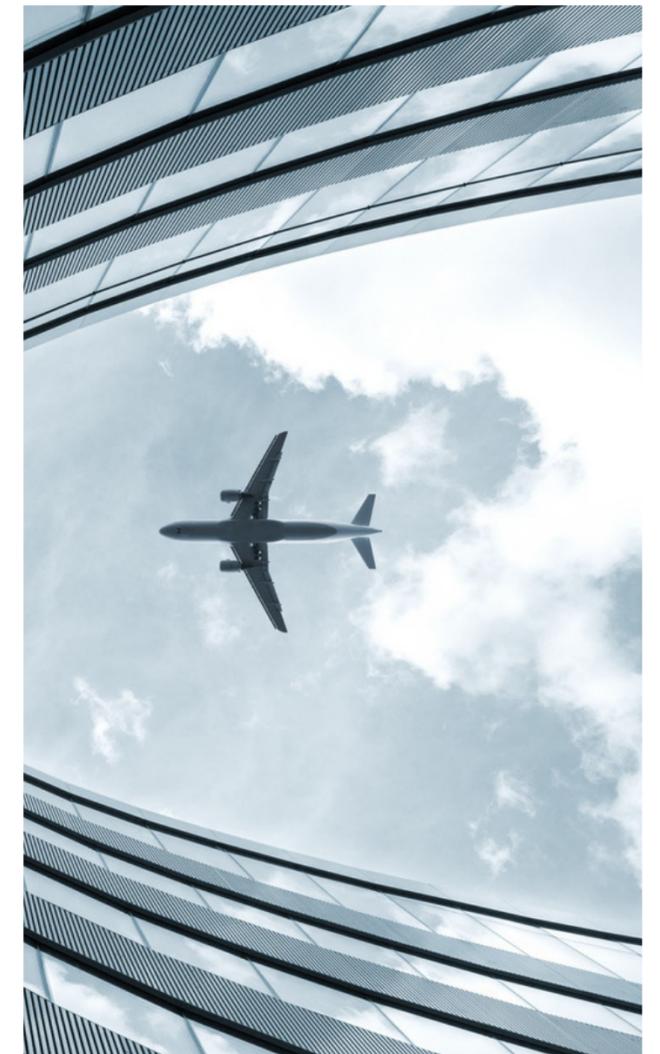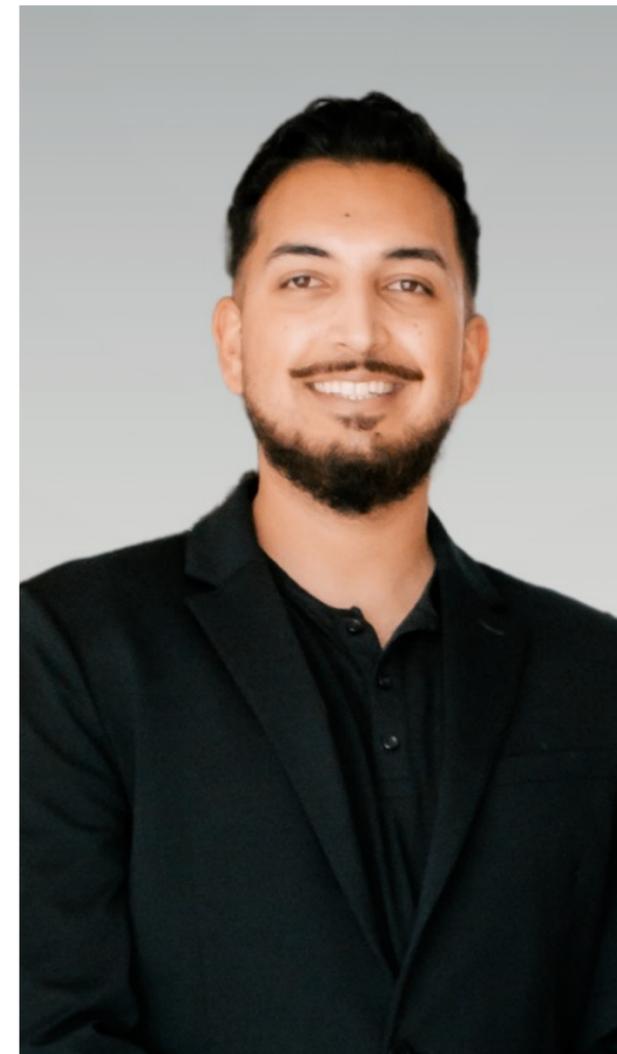
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